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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,123	NAKAGAMI ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination November 11, 2003 and Rule 132 Declaration filed on December 22, 2003 is acknowledged. Claims 1-16 and 18-20 are pending. Claim 17 is cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In instant case, the recitation "wherein the composition has a particle size ranging from 50 to 200 microns" does not have support. Instant specification page 16 states that the drug and wax have the instant particle size thorough primary granulation and the sugar alcohol is added after the primary granulation, thus applicant only has support for the instant particle sizes pertaining to the drug and wax combination and not for the entire composition. If applicant asserts there is support, the applicant is requested to provide the specific page and line providing support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 14-16, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Geyer et al (5,320,848).

Geyer et al disclose a chewable drug delivery composition for unpalatable drugs wherein the active agent is intimately dispersed on dissolved in a lipid. See abstract. Geyer et al define unpalatable as bad taste caused by acidity, bitterness, burning in the back of the throat, or malodor. See column 2, lines 44-45. Geyer discloses a particle size of 10 to 150 microns to provide for a pleasing mouth feel and texture upon chewing and swallowing. See column 4, line 14. The examples disclose an active (cimetidine, ibuprofen, aspirin, rantidine, erythromycin) melted with instant lipid (hydrogenated vegetable oil and tripalmitin) in instant ratio and mixed with sugar alcohol (sorbitol). The lipid has instant melting range. See example 1.

*It should be noted that claims 15-16 are product-by-process claims wherein patentability is based on the product itself and not the process in which it is made. See MPEP section 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geyer et al (5,320,848).

Geyer et al disclose a chewable drug delivery composition for unpalatable drugs wherein the active agent is intimately dispersed on dissolved in a lipid. See abstract. Geyer et al define unpalatable drugs as those having bad taste caused by acidity, bitterness, burning in the back of the throat, or malodor. See column 2, lines 44-45. Geyer discloses a particle size of 10 to 150 microns to provide for a pleasing mouth feel and texture upon chewing and swallowing. See column 4, line 14. The examples disclose an active (cimetidine, ibuprofen, aspirin, rantidine, erythromycin) melted with instant lipid (hydrogenated vegetable oil and tripalmitin) in instant ratio and mixed with sugar alcohol (sorbitol). The lipid has instant melting range. See example 1.

Geyer does not teach each and every instantly claimed active agents or sugar alcohols.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to use any active characterized by an unpleasant taste in Geyer et al's

inventive formulation. One would be motivated to do so since Geyer's formulation has the inventive purpose of masking the unpleasant taste of an active agent and Geyer teaches the incorporation of any active that is characterized by an unpleasant taste. The expected result would be a dosage form without an unpleasant taste. Further, it is deemed obvious to one of ordinary skill in the art to choose the sugar alcohol desired absent a showing of criticality since all the claimed sugar alcohols have the same functional equivalence.

Claims 1-16 and 18-20 under 35 U.S.C. 103(a) as being unpatentable over WO 93/17667 to Yakima et al in view of James et al (4,865,851).

Yajima et al teach a composition for oral preparation, which comprises a complex formed by dispersing or dissolving an unpleasantly tasting drug and a polymer in a substance having a low melting point, and a sugar alcohol (abstract). Yajima et al teach that the composition is excellent in masking unpleasantly tasting drugs and has excellent performance in biological use. More specifically Yajima teaches that the unpleasantly tasting drug can be erythromycin, or clarithromycin, among others (page 4, paragraph 2). Yajima et al teach that the substance having a low melting point if a water-insoluble or water sparingly soluble substance with a melting point of 40 to 120 degrees Celsius (page 4, paragraph 5), for example, hydrogenated oil, stearyl alcohol, glycerin fatty acid ester (page 5, paragraph 1). Yajima et al also teach that the sugar alcohol includes sorbitol, xylitol, and maltitol (page 5, paragraph 3) and that it is present at between 10 and 70 % by weight (page 5, paragraph 4). Yajima el al also teaches the

process of granulation through spray drying (see examples 1- 13). Lastly, Yajima et al teaches the composition as a dosage form for oral preparations.

The reference does not specify the instant particle sizes or it does not specifically teach each and every one of applicant's claimed active agents.

James et al teach a pharmaceutical composition comprising cefuroxime axetil in particulate form wherein the bitter taste of the active is masked. See abstract. James teaches the particle size is important for the bioavailability and consumer acceptability for oral administered drugs. Particle sizes above 250 microns are said to have an undesirable gritty taste and it is preferable that the taste-masked active has an average size of less than 100 microns, i.e. 20 to 100 microns. See column 4, lines 1-10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yajima et al and James et al and utilize the instant particle size range. One would be motivated to do so since James et al teach the use of particle sizes above 250 microns provide for a gritty feel and low bioavailability. Further, James teaches the preferable range of less than 100 microns, i.e. 20 to 100 microns, which is within applicant's claimed range. Lastly, both references have the same inventive purpose of masking the taste of unpleasant tasting actives and this one would expect similar results by combining the references. Therefore, yielding an improved dosage form without a unpleasant taster that not only contains a formulation that masks the bitter taste of the active but also having particles sizes which improve mouth feel.

Lastly, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to use any active characterized by an unpleasant taste in Yajima et al's inventive formulation. One would be motivated to do so since Yajima's formulation has the inventive purpose of masking the unpleasant taste of the active agent. The expected result would be a dosage form without an unpleasant taste.

Response to Amendment

The Declaration under 37 CFR 1.132 filed December 22, 2003 is insufficient to overcome the rejection of claims 1-16 and 18-20 based upon WO 93/17667 to Yakima et al as set forth in the last Office action for the following reasons:

The applicant states that the enclosed data demonstrates that the particle size range of 50 to 200 microns brings substantial improvement to the qualities of the claimed invention such as enhancing favorable sensation and preventing throat irritation. It is pointed out that the claims recite a generic drug, wax, and sugar alcohol without reciting any concentration parameters. It is firstly noted that applicant does not utilize the same composition as claimed, i.e. the claims require a sugar alcohol and the instant examples do not contain a sugar alcohol. It is secondly noted that the submitted Declaration utilizes a specific wax and drug in a specific concentration. Thus, the claims are not commensurate in scope. A single specific formulation does not establish a generic concept.

Miscellaneous Matters

It is noted that upon submission of the amended claims to be considered, the applicant did not submit claims 16, 18, or 20. Although these claims have been given

consideration on the merits in this office action, applicant is requested to file a complete copy of all pending claims in subsequent responses. Failure to do so will cause applicant to receive a non-complaint letter and delay in prosecution.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

April 2, 2004

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